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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|--------------------------|---------------------|------------------|
| 10/569,710  | 03/08/2007  | Daniel Jacobus Steenkamp | 169-87441           | 7959             |
| 22342 7590 05/21/2008<br>FITCH EVEN TABIN AND FLANNERY<br>120 SOUTH LA SALLE STREET<br>SUITE 1600<br>CHICAGO, IL 60603-3406 |             |                          |                     |                  |
| EXAMINER<br>NWAONICHA, CHUKWUMA O   |             |                          |                     |                  |
| ART UNIT  |             | PAPER NUMBER             |                     |                  |
| 1621  |             |                          |                     |                  |
| MAIL DATE   |             | DELIVERY MODE            |                     |                  |
| 05/21/2008  |             | PAPER                    |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/569,710

**Applicant(s)**

STEENKAMP, DANIEL JACOBUS

**Examiner**

CHUKWUMA O. NWAONICHA

**Art Unit**

1621

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) \_\_\_\_\_ is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-9 and 11-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date: \_\_\_\_\_

**DETAILED ACTION**

***Current Status***

1. This action is responsive to Applicants' amendment of 14 February 2008.
2. Receipt and entry of Applicants' amendments is acknowledged.
3. Claims 1, 2, 5-9 and 11-18 are pending in the application.
4. The 112, 103 and 102 rejections have been withdrawn in favor of the current rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5-9 and 11-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for specifically "2-thiopyridyl-6-hydroxynaphthyl disulphide, 1-D-myo-inositol-2-deoxy-2-(N-acetyl-L-cysteinyl)amino-.alpha.-D-glucopyranoside, or mycothiol" does not reasonably provide enablement for "any disulphide, any thiol, any polynuclear aromatic group or any hydrophobic moiety" as claimed.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The standard for determining whether the specification meets the enablement requirement is whether experimentation needed to practice the invention is undue or unreasonable. Accordingly, even though the forgoing statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. See M.P.E.P. § 2164.

In the instant case, the claims cover "any disulphide, any thiol, any polynuclear aromatic group or any hydrophobic moiety". Based on the above standards, the disclosure must contained sufficient information to enable one skilled in the pertinent art to practice this invention without undue experimentation. See M.P.E.P. 2164.01. Given the lack of disclosure of "any disulphide, any thiol, any polynuclear aromatic group or any hydrophobic moiety", the instant invention cannot be practiced commensurate in scope with the claims.

The Examiner understands that there is no requirement that the specification disclose every possible embodiment if there is sufficient guidance given by knowledge in the art (See M.P.E.P. § 2164.05(a)). However, the instant case goes beyond what is known in the art, because the specification does not offer any guidance on how one of ordinary skill would go about practicing the invention from the claim to "any disulphide, any thiol, any polynuclear aromatic group or any hydrophobic moiety".

Here, the requirement for enablement is not met since the claims go far beyond the enabling disclosure. Based on the forgoing, **claims 1, 2, 5-9 and 11-18** are *prima facie* non-enabled for their full scope.

With regard to rejection under 35 U. S. C. 112, first paragraph, the following factors have been carefully considered (*In re Wands*, 8 USPQ2d 1400; CAFC, 1988):

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

(1) **Nature of the invention.** As indicated above, the invention is drawn to “any disulphide, any thiol, any polynuclear aromatic group or any hydrophobic moiety”.

(2) **Breadth of the Claims.** The claims are extremely broad. In particular, **claims 1, 2, 5-9 and 11-18** that read on specifically “any disulphide, any thiol, any polynuclear aromatic group or any hydrophobic moiety”.

(4) **Unpredictability of the Art.** The instant case is drawn to “any disulphide, any thiol, any polynuclear aromatic group or any hydrophobic moiety”. Any “disulphide, any thiol, any polynuclear aromatic group or any hydrophobic moiety” as claimed is speculative. Applicants’ claim “any disulphide, any thiol, any polynuclear aromatic group or any hydrophobic moiety” is doubtful and requires objective proof. In such a speculative field, more enablement by way of specific examples is necessary in order to establish the utility of a genus. *In re Fisher*, 166 U.S.P.Q. 18.

(5) **Amount of Guidance Provided.** Applicants have provided guidance as how to employ “2-thiopyridyl-6-hydroxynaphthyl disulphide, 1-D-myo-inositol-2-deoxy-2-(N-acetyl-L-cysteinyl)amino-.alpha.-D-glucopyranoside, or mycothiol”. However, when

considering that the claims read on the “any disulphide, any thiol, any polynuclear aromatic group or any hydrophobic moiety”, it becomes critical to know all “disulphides, thiols, polynuclear aromatic groups or hydrophobic moieties” that applicants are claiming. This is critical to the practice of the invention and therefore should adequately be disclosed.

(7) **Ordinary Skill in the Art.** The ordinary skill artisan would not be able to practice the claimed invention with the current disclosure. It is not clear how to employ “any disulphide, any thiol, any polynuclear aromatic group or any hydrophobic moiety” that applicant are claiming.

Thus, it can safely be concluded that the instant disclosure fails to provide an enabling disclosure for “any disulphide, any thiol, any polynuclear aromatic group or any hydrophobic moiety” as claimed.

**The Examiner suggests that Applicants combined claims 13 and 14 into claim 1, and re-define the variables: R, R' and R”.**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chukwuma O. Nwaonicha whose telephone number is 571-272-2908. The examiner can normally be reached on Monday thru Friday, 8:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne (Bonnie) Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1621

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Chukwuma O. Nwaonicha/  
Examiner, Art Unit 1621

(for)

/Sikarl A. Witherspoon/  
Primary Examiner, Art Unit 1621

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Yvonne (Bonnie) Eyler  
Supervisory Patent Examiner,  
Technology Center 1600